

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	WAGNER et al.	Examiner:	Unassigned
Serial No.:	Unassigned	Group Art Unit:	Unassigned
Filed:	March 12, 2004	Docket No.:	GUID.627PA
Title:	PATIENT STRATIFICATION FOR IMPLANTABLE SUBCUTANEOUS CARDIAC MONITORING AND THERAPY		

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CERTIFICATE UNDER 37 CFR 1.10  
Express Mail<sup>®</sup> mailing label number: EV 381020377 US  
Date of Deposit: March 12, 2004  
I hereby certify that this paper or fee is being deposited with the United States Postal Service 'Express Mail  
Post Office To Addressee' service under 37 CFR 1.10 and is addressed to the Commissioner for Patents,  
MAIL STOP PATENT APPLICATION, P.O. Box 1450, Alexandria, VA 22313-1450.  
By: Kelly S. Waltigney  
Name: Kelly S. Waltigney

**INFORMATION DISCLOSURE STATEMENT (37 C.F.R. §1.97(b))**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner.

This statement should be considered because it is submitted either within three months of the filing date or before the first Office Action of the above-identified application. Accordingly, no fee is due for consideration of the items listed on the enclosed Form 1449.

In accordance with 37 C.F.R. §1.98(a)(2), and the 05 August 2003 Official Gazette Notice, only a copy of each foreign document or non-U.S. patent/application listed on the enclosed Form 1449 is provided.

Please note that any notations or markings on the attached documents do not reflect particular relevance, or lack thereof, to the present application, nor were they necessarily made by anyone affiliated with the prosecution of the present application.

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the reference(s) are not "prior art." Moreover, Applicants do not represent that a reference has been thoroughly reviewed or that any relevance of any portion of a reference is intended.

Applicant brings to the Examiner's attention commonly owned, co-pending U.S. Application 10/465,520, filed June 19, 2003, which may be of interest.

Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form 1449, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

Respectfully submitted,

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Suite 390  
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Date: March 12, 2004

By: 

Mark A. Hollingsworth  
Reg. No. 38,491

<b>FORM 1449*</b>  <b>INFORMATION DISCLOSURE STATEMENT</b>  <b>IN AN APPLICATION</b>  (Use several sheets if necessary)	Docket Number: GUID.627PA	Application Number: To be assigned
	Applicant: WAGNER <i>et al.</i>	
	Filing Date: 3/12/2004	Group Art Unit: To be assigned

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	6,628,986 B1	09/30/03	Mouchawar et al.			
	6,622,046	09/16/03	Fraley et al.			
	6,615,083	09/02/03	Kupper			
	6,607,509	08/19/03	Bobroff et al.			
	6,564,106	05/13/03	Guck et al.			
	6,522,915	02/18/03	Ceballos et al.			
	6,512,940	01/28/03	Brabec et al.			
	6,491,639	12/10/2002	Turcott			
	6,487,443	11/26/02	Olson et al.			
	6,438,410	08/20/02	Hsu et al.			
	6,280,462	08/28/01	Hauser et al.			
	6,259,947	07/10/01	Olson et al.			
	6,148,230	11/14/00	KenKnight			
	6,141,581	10/31/00	Olson et al.			
	6,055,454	04/25/00	Heemels			
	6,044,298	03/28/00	Salo et al.			
	5,957,956	09/28/99	Kroll et al.			
	5,916,243	06/29/99	KenKnight et al.			
	5,895,414	04/20/99	Sanchez-Zambrano			
	5,855,593	01/05/99	Olson et al.			
	5,836,987	11/17/98	Baumann et al.			
	5,827,326	10/27/98	Kroll et al.			
	5,724,984	03/10/98	Arnold et al.			
	5,704,365	01/06/98	Albrecht et al.			
	5,697,953	12/16/97	Kroll et al.			
	5,662,688	09/02/97	Haefner et al.			
	5,641,326	06/24/97	Adams			
	5,634,938	06/03/97	Swanson et al.			
	5,620,466	04/15/97	Haefner et al.			
	5,603,732	02/18/97	Dahl et al.			

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.	

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	5,545,202	08/13/96	Dahl et al.			
	5,545,186	08/13/96	Olson et al.			
	5,540,727	07/30/96	Tockman et al.			
	5,531,779	07/02/96	Dahl et al.			
	5,468,254	11/21/95	Hahn et al.			
	5,441,518	08/15/95	Adams et al.			
	5,439,482	08/08/95	Adams et al.			
	5,411,539	05/02/95	Neisz			
	5,411,525	05/02/95	Swanson et al.			
	5,411,031	05/02/95	Yomtov			
	5,397,342	03/14/95	Heil, Jr. et al.			
	5,391,200	02/21/95	KenKnight et al.			
	5,388,578	02/14/95	Yomtov et al.			
	5,376,106	12/27/94	Stahmann et al.			
	5,372,606	12/13/94	Lang et al.			
	5,366,496	11/22/94	Dahl et al.			
	5,360,442	11/01/94	Dahl et al.			
	5,331,966	07/26/94	Bennett et al.			
	5,318,597	06/07/94	Hauck et al.			
	5,314,459	05/24/94	Swanson et al.			
	5,314,430	05/24/94	Bardy			
	5,313,953	05/24/94	Yomtov et al.			
	5,301,677	04/12/94	Hsung			
	5,300,106	04/05/94	Dahl et al.			
	5,292,338	03/08/94	Bardy			
	5,284,136	02/08/94	Hauck et al.			
	5,261,400	11/16/93	Bardy			
	5,230,337	07/27/93	Dahl et al.			
	5,209,229	05/11/93	Gilli			
	5,203,348	04/20/93	Dahl et al.			
	5,179,945	01/19/93	Van Hofwegen et al.			
	5,170,784	12/15/92	Ramon et al.			

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	5,133,353	07/28/92	Hauser			
	5,036,849	08/06/91	Hauck et al.			
	4,953,551	09/04/90	Mehra et al.			
	4,562,841	01/07/86	Brockway et al.			
	2003/0212436	11/13/03	Brown			
	2003/0097153	05/22/03	Bardy et al.			
	2003/0088286	05/08/03	Ostroff et al.			
	2003/0088283	05/08/03	Ostroff			
	2003/0088282	05/08/03	Ostroff			
	2003/0088281	05/08/03	Ostroff et al.			
	2003/0088280	05/08/03	Ostroff			
	2003/0088279	05/08/03	Rissmann et al.			
	2003/0088278	05/08/03	Bardy et al.			
	2003/0069609	04/10/03	Thompson			
	2003/0045904	03/06/03	Bardy et al.			
	2003/0036778	02/20/03	Ostroff et al.			
	2003/0023175	01/30/03	Arzbaeher et al.			
	2003/0004552	01/02/03	Plombon et al.			
	2003/0004546	01/02/03	Casey			
	2002/0120299	08/29/02	Ostroff et al.			
	2002/0107559	08/08/02	Sanders et al.			
	2002/0107549	08/08/02	Bardy et al.			
	2002/0107548	08/08/02	Bardy et al.			
	2002/0107547	08/08/02	Erlinger et al.			
	2002/0107546	08/08/02	Ostroff et al.			
	2002/0107545	08/08/02	Rissmann et al.			
	2002/0107544	08/08/02	Ostroff et al.			
	2002/0103510	08/01/02	Bardy et al.			
	2002/0095184	07/18/02	Bardy et al.			
	2002/0091414	07/11/02	Bardy et al.			
	2002/0082658	06/27/02	Heinrich et al.			
	2002/0072773	06/13/02	Bardy et al.			

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	2002/0068958	06/06/02	Bardy et al.			
	2002/0052636	05/02/02	Bardy et al.			
	2002/0049476	04/25/02	Bardy et al.			
	2002/0049475	04/25/02	Bardy et al.			
	2002/0042634	04/11/02	Bardy et al.			
	2002/0042630	04/11/02	Bardy et al.			
	2002/0042629	04/11/02	Bardy et al.			
	2002/0035381	03/21/02	Bardy et al.			
	2002/0035380	03/21/02	Rissmann et al.			
	2002/0035379	03/21/02	Bardy et al.			
	2002/0035378	03/21/02	Bardy et al.			
	2002/0035377	03/21/02	Bardy et al.			
	2002/0035376	03/21/02	Bardy et al.			

FOREIGN PATENT DOCUMENTS						
DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
WO 92/20402	26 Nov. 1992	WO			YES	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)						
		Renee Hartz <i>et al.</i> , <i>New Approach to Defibrillator Insertion</i> , J. Thoracic Cardiovascular Surgery, Vol. 97, pp. 920-922 (1989).				
		Theofilos M. Kolettis, MD, PhD <i>et al.</i> , <i>Submammary Implantation of a Cardioverter-Defibrillator with a Nonthoractomy Lead System</i> , Am. Heart J., Vol. 126, pp. 1222-1223 (Nov. 1993)				
		John C. Schuder <i>et al.</i> , <i>Transthoracic Ventricular Defibrillation in the Dog with Truncated and Untruncated Exponential Stimuli</i> , IEEE Trans. On Bio-Medical Engin., Vol. BME-18, No. 6, pp. 410-415 (Nov. 1971).				
		John C. Schuder <i>et al.</i> , <i>Ventricular Defibrillation in the Dog Using Implanted and Partially Implanted Electrode Systems</i> , Am. J. of Cardiology, Vol. 33, pp. 243-247 (Feb. 1974).				
		John C. Schuder <i>et al.</i> , <i>Experimental Ventricular Defibrillation with an Automatic and Completely Implanted System</i> , Trans. Am. Soc. Artif. Int. Organs, Vol. 16, pp. 207-212 (1970).				
		Karel Smits & Marek Malik, <i>Defibrillation Threshold (DFT) Model of a Fully Subcutaneous ICD System</i> , Europace Supplements, Vol. 2, June 2001, page B83, column 778 (best copy available).				
		Stirbis <i>et al.</i> , <i>Optimizing the Shape of Implanted Artificial Pacemakers</i> , Kaunas Medical Institute. Translated from Meditsinskaya Tekhnika, No. 6, pp. 25-27 (1986).				
		Charles T. Leng <i>et al.</i> , <i>Lead Configuration for Defibrillator Implantation in a Patient with Congenital Heart Disease and a Mechanical Prosthetic Tricuspid Valve</i> , PACE, Vol. 24, No. 8, pp. 1291-1292 (Aug. 2001).				
		Park & Pollock, <i>Use of an Implantable Cardioverter Defibrillator in an Eight-Month-Old Infant with Ventricular Fibrillation Arising from a Myocardial Fibroma</i> , PACE, Vol. 22, No. 1, pp. 138-139 (Jan. 1999).				
		Rainer Gradaus M.D. <i>et al.</i> , <i>Nonthoracotomy Implantable Cardioverter Defibrillator Placement in Children: Use of a Subcutaneous Array Leads and Abdominally Placed Implantable Cardioverter Defibrillators in Children</i> , J. of Cardiovascular Electrophysiology, Vol. 12, No. 3, pp. 356-360 (March 2001)				

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